UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

MSP RECOVERY CLAIMS, SERIES LLC,	**CASE NO.: 3:18-cv-01163-JZ**
Plaintiff,	**HONORABLE JACK ZOUHARY**
v.	**CLASS ACTION**
INSYS THERAPEUTICS, INC.,	**DEMAND FOR JURY TRIAL**
Defendant.	

FIRST AMENDED CLASS ACTION COMPLAINT

MSP Recovery Claims, Series LLC, a Delaware entity, ("Plaintiff"), by and through the undersigned counsel, hereby files this First Amended Class Action Complaint against Insys Therapeutics, Inc., (hereinafter "Defendant" or "Insys"), and alleges as follows:

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INTRODUCTION

1. This action seeks relief under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961, *et* seq., and common law arising from the highly successful and fraudulent scheme by Insys, the manufacturer of a fentanyl opioid sublingual medication, Subsys, to wrongfully induce healthcare benefit payers, including Plaintiff's Assignors, into paying for inappropriate off-label prescriptions of Subsys for unapproved uses and at larger than necessary dosages.

2. Subsys, if properly prescribed, is approved for use only in opioid tolerant patients with serious breakthrough cancer pain.

3. This extremely narrow market, estimated to be one to two million patients in the United States, was the first limitation Insys faced in selling Subsys, which was its only product line and sole source of revenue at the time. The second problem for Insys was that payers like Plaintiff's Assignors were, in making coverage decisions, effectively screening out improper, non-covered Subsys prescriptions and were declining to authorize coverage for roughly 70% of all prior authorization requests when Subsys was first released for sale.

4. Insys overcame these obstacles and turned Subsys into a billion-dollar drug through an illegal scheme that induced doctors into prescribing Subsys to often vulnerable and unsuspecting patients who never should have received such a dangerous and expensive drug.

5. To monetize wholly inappropriate and lethally dangerous "off-label" Subsys prescriptions, Insys needed to induce or trick payers like Plaintiff's Assignors to pay for them. Insys solved its problem by creating an in-house "prior authorization department" ("PAD") whose entire existence was dedicated to wrongfully inducing authorization for payments of Subsys. The venal methods employed by Insys' employees in the PAD and their co-conspirators were shocking. These employees impersonated physicians' medical office staff, used fake names, spoofed fake area codes, and invented cancer diagnoses to wrongfully induce or defraud Plaintiff's Assignors into authorizing coverage of Subsys.

6. Based on money improperly received from this scheme, Insys' revenues soared.

7. Recently, however, the vast scope of Insys' illegal scheme has come to light. Its senior officers, executives, sales staff, and prior authorization staff have either pleaded guilty or have been indicted for fraud and violation of the federal anti-kickback statutes, 18 U.S.C. §§ 371 and 982(a)(7). The doctors and practitioners Insys bribed to prescribe Subsys off-label have been sanctioned, convicted or are under current criminal investigation, and the families of patients who have died due to Insys' misconduct are seeking redress in court.

8. The foregoing allegations establish that Defendant entered into a years-long pattern of conspiracy, tortious misconduct, insurance fraud, negligent misrepresentation, negligence, and common law fraud, and were unjustly enriched at Plaintiff's expense. This misconduct began on or about January 4, 2012, the date on which Subsys was approved for its specific use in treating opioid-tolerant patients experiencing cancer-related breakthrough pain. However, the conduct was not known to Plaintiff until 2017.

9. As detailed in the U.S. Senate Committee on Homeland Security and Governmental Affairs, Ranking Member's Office's released report "Fueling an Epidemic: Insys Therapeutics and

the Systemic Manipulation of Prior Authorization," Insys knew about its problematic prior authorization practices and that it "lacked formal policies or monitoring procedures to ensure proper communication between Insys employees and healthcare professionals" but failed to implement "sufficient compliance processes to prevent fraud and was internally aware of the danger of problematic practices."[1]

10. Plaintiff brings this action for fraud and violation of the RICO statute to recover damages it is due because of Insys' fraudulent scheme and conspiracy for the off-label prescriptions, sales and promotions of Subsys.

PARTIES

11. Plaintiff MSP Recovery Claims, Series LLC, is a Delaware entity with its principal place of business located at 5000 S.W. 75th Avenue, Suite 400, Miami, Florida 33155. Numerous Medicare Advantage Organizations ("MAOs"), Independent Practice Associations ("IPAs"), Management Service Organizations ("MSOs"), Health Maintenance Organizations ("HMOs"), and other Medicare downstream entities across the United States have assigned their rights to MSP Recovery Claims, Series LLC. These assignments include the right to recover payments for fraudulently-obtained Subsys prescriptions. As a result of these assignments, MSP Recovery Claims, Series LLC, is empowered and has standing herein to pursue the claims of its Assignors and other third-party payers that paid for Subsys prescriptions obtained through the Defendant's pattern of racketeering activity and fraudulent practices. Accordingly, Plaintiff, MSP Recovery

[1]U.S. Senate, Committee on Homeland Security & Governmental Affairs, *Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization*, 4 (Sept. 6, 2017), *available at* https://www.mccaskill.senate.gov/media-center/news-releases/breaking-mccaskill-opioid-investigation-releases-first-report-detailing-systemic-manipulation-of-prior-authorization-process-by-insys-therapeutics- (last visited March 9, 2018).

Claims, Series LLC, by assignment, has suffered damages and now seeks reimbursement for the money lost by these Assignors and other third-party payers that were fraudulently induced to pay for claims related to Subsys prescriptions.

12. Between January 2012 until the present, Plaintiff's Assignors paid a substantial amount of money for inappropriate off-label prescriptions of Subsys.

13. Defendant Insys Therapeutics, Inc. is a corporation organized under the laws of the State of Delaware and is headquartered in Chandler, Arizona. Insys designed and manufactured the drug Subsys, which it distributed, marketed and sold to Plaintiff's Assignors' members throughout the United States.

14. The parties identified herein, as well as the Unnamed Co-Conspirators discussed below, are "Enterprise participants" as set forth below.

15. Unnamed Co-Conspirators: Although not named as parties, the following co-conspirators violated 18 U.S.C. §§ 1962 (c) and (d) by actively participating in Insys' scheme to market Subsys for off-label uses and fraudulently concealing Insys' role in participating in this scheme, which had the intended result of defrauding Plaintiff's Assignors and the members of the putative Class:

a. Michael L. Babich ("Babich") was at relevant times the President and Chief Executive Officer ("CEO") of Insys. As President and CEO of Insys, Babich was responsible for managing the development, promotion, distribution, and sale of Subsys. Babich resided in Scottsdale, Arizona.

b. Alec Burlakoff ("Burlakoff") held executive management positions at Insys at relevant times including Regional Sales Manager for the Southeast Region and Vice President of Sales. Burlakoff resided in Charlotte, North Carolina.

c. Michael J. Gurry ("Gurry") held executive management positions at Insys at relevant times including Vice President of Managed Markets. Gurry resided in Scottsdale, Arizona.

d. Richard M. Simon ("Simon") held executive management positions at Insys at relevant times including Regional Sales Manager for the Central Region and National Director of Sales. Simon resided in Seal Beach, California.

e. Sunrise Lee ("Lee") held executive management positions at Insys at relevant times including Regional Sales Manager for the Mid-Atlantic Region, Regional Director for the Central Region, and Regional Director for the West Region. Lee resided in Byron Center, Michigan.

f. Joseph A. Rowan ("Rowan') held executive management positions at Insys at relevant times including Regional Sales Manager for the Southeast Region and Regional Director for the East Region. Rowan resided in Panama City, Florida.

g. Babich, Burlakoff, Gurry, Simon, Lee and Rowan are collectively referred to as the "Insys Executive Co-Conspirators."

h. The Insys Executive Co-Conspirators acted on behalf of Insys when they took the actions described in this Complaint because they knew and intended that Insys would be the primary beneficiary of the conspiracy to defraud Plaintiff's Assignors.

i. The Insys Executive Co-Conspirators were acting within the scope of their employment when they took the actions described in this Complaint because the purpose of their conspiracy was to (1) increase the number of Subsys prescriptions, and (2) defraud payers like Plaintiff's Assignors into paying for these prescriptions under false pretenses.

j. Licensed medical practitioners who Insys paid through its' fraudulent speakers' program to promote Subsys for off-label use.

k. Licensed medical practitioners who were registered with the Drug Enforcement Administration ("DEA") and are believed to be able to prescribe opioids, such as Subsys, in the course of their professional practice only for an indicated and legitimate medical purpose. As prescribers of Transmucosal Immediate-Release Fentanyl ("TIRF") drugs, John Does 1-10 also were required to enroll in the TIRF Risk Evaluation and Mitigation Strategy ("REMS") Access Program ("the Program") and participated in the conspiracy by improperly prescribing Subsys to Plaintiff's Assignors' members.

l. These prescribers had a legal and fiduciary duty to refrain from accepting or agreeing to accept bribes and kickbacks in exchange for prescribing any drug. At all relevant times, these licensed medical practitioners engaged in various illegal activities with the Defendant and other unknown persons and entities to defraud payers, including Plaintiff's Assignors, as described in this Complaint.

m. Pharmacies that filled Subsys prescriptions without questioning the volume, dosage, or diagnosis for which Subsys was prescribed.

16. Defendant and the Unnamed Co-Conspirators knew or should have known that Plaintiff's Assignors only provided healthcare benefits for Subsys for its FDA approved use and conditions.

17. Defendant and the Unnamed Co-Conspirators knew or should have known that Plaintiff's Assignors would rely upon their misrepresentations, omissions and falsehoods in paying for benefits on behalf of members that were not properly payable.

18. Defendant and the Unnamed Co-Conspirators knew or should have known that Plaintiff's Assignors would rely upon their misrepresentations, material omissions and falsehoods.

STANDING

21. Plaintiffs have been assigned all legal rights of recovery and reimbursement for health care services and Medicare benefits provided by MAOs, HMOs, MSOs, IPAs, and other downstream entities (collectively, the "Assignors"), that administer Medicare benefits for Medicare beneficiaries under Medicare Part C and/or Medicare Part D; whether said rights arise from (i) contractual agreements, such as participation and network agreements with capitation and risk sharing arrangements, and/or (ii) state and federal laws that provide for the reimbursement of payments made by the assignor health plans, including the right to recover claims for health care services on a fee-for-service basis.

19. At all material times hereto, one of Plaintiff's Assignors provided Medicare benefits to MA plan beneficiaries, including payment for the beneficiaries' Subsys prescription. For instance, on 5/12/2017, SummaCare, Inc. entered into an assignment with MSP Recovery, LLC. Said assignment included the following language "[c]lient hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client's right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for Client that Client had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to client arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating

thereto, all of which shall constitute the "Assigned Claims”.” The assignment contract was executed by individuals of majority, of sound mind, and with legal authority to bind the respective parties. The assignment was entered into under Ohio law. On 6/12/2017, MSP Recovery, LLC entered into an assignment with MSP Recovery Claims, Series LLC, irrevocably assigning its right to recover payments as assigned from SummaCare, Inc. This assignment was made pursuant to the Series 16-11-509 assignment. This second assignment contract was executed by individuals of majority, of sound mind, and with legal authority to bind the respective parties. This second assignment was entered into under Delaware law. Consideration was given between each party in executing these assignments.

JURISDICTION

22. The United States District Court for the Northern District of Ohio has subject-matter jurisdiction pursuant to 28 U.S.C. § 1332(d). At least one member of the putative class is a citizen of a different state than Defendant, and the aggregate amount in controversy exceeds $5,000,000, exclusive of interest and costs.

23. The United States District Court for the Northern District of Ohio also has federal question jurisdiction pursuant to 28 U.S.C. § 1331. The causes of action alleged in this First Amended Complaint arises under the laws of the United States.

24. The Court has personal jurisdiction over Defendant. Defendant has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of the illegal scheme and conspiracy throughout the United States, including the State of Ohio and in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States,

including in this judicial district. 15 U.S.C. Section 22 provides for nationwide service of process. This Court also has personal jurisdiction over Defendant pursuant to Fed. R. Civ. P. 4(k)(1)(A) because it would be subject to the jurisdiction of a court of general jurisdiction in the State of Ohio.

25. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c), because Defendant transacts business in, is found in, and/or has agents in the State of Ohio, and because some of the actions giving rise to this Complaint took place within this district in Bellevue, Ohio (*see* Exhibit A).

BACKGROUND
MEDICARE ALLEGATIONS

26. Plaintiff is the assignee of Medicare Part C and/or Medicare Part D prescription drug coverage providers on behalf of thousands of individual beneficiaries.

The Social Security Act

27. The Medicare Act is found within the Social Security Act under Title XVIII. The Social Security Act was enacted on August 14, 1935. *See Soc. Sec. Admin., https://www.ssa.gov/history/1930.html (last visited March 20, 2018).* A few years thereafter, the law added benefits for a retiree's spouse, as well as children and disability benefits. *Id.* It is "the foundation of economic security for millions of Americans—retirees, disabled persons, and families of retired, disabled or deceased workers. About 163 million Americans pay Social Security taxes and 59 million collect monthly benefits. About one family in four receives income from Social Security." *See* Nat. Academy of Soc. Ins., https://www.nasi.org/learn/socialsecurity/overview (last visited March 20, 2018).

28. The Social Security System uses taxpayer money to pay benefits to retirees, the disabled, survivors of workers who have died, and dependents of beneficiaries. *See Understanding the Benefits, Social Security Administration, 4 (March 2016), https://www.ssa.gov/pubs/EN-05-*

10024.pdf. Any unused money goes to the Social Security trust fund. *Id*. "Nearly 84 percent of all people 65 and older ("Seniors") receive social security." *Nat. Academy of Soc. Ins., 4 (Aug. 2016), https://www.nasi.org/sites/default/files/research/2016_Social_Security_Primer.pdf (last visited March 20, 2018)*. In 1965, Congress amended the Social Security Act to create the Medicare Act under Title XVIII.

The Medicare Act

29. The Medicare Act functions as a "federally funded health insurance program for the elderly and the disabled." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 506 (1993). The Medicare Act consists of five parts — Part A, B, C, D and E. Part A and Part B "create, describe, and regulate traditional fee-for-service, government-administered Medicare." *In re Avandia Mktg. Sales Practices and Products Liability Litigation*, 685 F.3d 353, 357 (3d Cir. 2012) (citing 42 U.S.C. §§ 1395c to 1395i-5; 1395j to 1395w). Part C outlines the Medicare Advantage program and provides that Medicare beneficiaries may elect for private insurers to deliver their Medicare benefits to them. 42 U.S.C. §§ 1395w-21-29. Further, Part D provides for prescription drug coverage to Medicare beneficiaries, and Part E contains miscellaneous provisions related to 42 U.S.C. §§ 1395x, 1395y.

The Medicare Part C Program

30. Since the 1970s, Medicare beneficiaries have had the option to receive their Medicare benefits through private health plans, mainly Health Maintenance Organizations ("HMOs"), as an alternative to the federally administered traditional Medicare programs. Kaiser Family Foundation, http://kff.org/medicare/fact-sheet/medicare-advantage/ (last visited March 22, 2018). The Balanced Budget Act of 1997 named Medicare's managed care program "Medicare+Choice" and the Medicare Modernization Act (MMA) of 2003 renamed it "Medicare

Advantage." *Id., See also Collins v. Wellcare Healthcare Plans, Inc.*, 73 F. Supp. 3d 653, 659 (E.D. La. 2014). "The congressional goal in creating the Medicare Part C option was to harness the power of private sector competition to stimulate experimentation and innovation to create a more efficient and less expensive Medicare system." D. Gary Reed, Medicare Advantage Misconceptions Abound, 27 Health Law 1, 3 (2014). Congress sought to achieve this goal by implementing a program wherein the government would pay private health insurers a flat rate per enrollee to administer and provide the same basic benefits received under traditional Medicare. *See Honey v. Bayhealth Med. Ctr., Inc*., 2015 Del. Super. LEXIS 378, at *7-17 (Del. Super. Ct. July 28, 2015). Pursuant to this framework, an MAO pays providers directly for the care received by Part C enrollees. *Id*. at *10. To the extent that this care exceeds the flat rate received from the government, an MAO assumes the risk and cost. *Id*. In the event that care costs less than the flat rate received, an MAO is permitted to keep the difference as a profit. *Id.*

31. To be approved to be an MAO, a private insurer must enter a bidding process, meeting certain threshold requirements. *Id*. MAOs must also be licensed in each state in which they operate. *Id*. MAOs must offer an "[evidence] of coverage" annually, approved by CMS to enrollees. Id. In providing the basic benefits offered to traditional Medicare enrollees, MAOs must abide by national coverage determinations provided by CMS. *Id*. In addition, all coverage disputes between enrollees, and MAOs must go through the traditional Medicare appeals process. *Id*. at *11. The decisions coming out of the Medicare appeals process are, moreover, binding upon an MAO. *Id*.

32. It is the federal government which sets the fixed rate at which MAOs will be remunerated. *Id*. at *12. Likewise, the federal government establishes the basic services that each Part C private insurer participant must provide. *Id*. These private health insurers are, further,

constrained in their ability to deny coverage, limited to the decisions of federally anointed adjudicators. *Id*. The discretion permitted to these private insurers is within this federally created framework – not outside or even alongside it. *Id*. at *12-13. Under Part C, the contract is between the federal government and the insurer. *Id*. at *13.

33. An enrollee's health coverage with an MAO is strictly construed and regulated by CMS. *Id*. So much so that CMS provides detailed templates for MAOs to use when they create documents, including an evidence of coverage that is provided to enrollees. *See* CMS, https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial.html (last visited March 20, 2018).

34. **Medicare Part C is the functional equivalent of original Medicare**. *See* 42 C.F.R. §§ 422.108(f), 422.101; *Honey v. Bayhealth Med. Ctr., Inc.*, 2015 Del. Super. LEXIS 378, at *18 (Del. Super. Ct. July 28, 2015) (holding "an MAO is squarely within the traditional Medicare system").

35. By way of background, Plaintiff's Assignors entered into a contract with CMS to provide Medicare benefits in accordance with the Medicare Part C program to Medicare-eligible enrollees and, in return, received a per capita fee from CMS. *See Humana Med. Plan, Inc. v. W. Heritage Ins. Co*., 2016 U.S. App. LEXIS 14509, at *11 (11th Cir. 2016) ("Under the Medicare Advantage program, a private insurance company, operating as an MAO, administers the provision of Medicare benefits pursuant to a contract with CMS. CMS pays the MAO a fixed fee per enrollee, and the MAO provides at least the same benefits as an enrollee would receive under traditional Medicare."); *See also* 42 U.S.C. §§ 1395w-22(a), 1395w-23. Therefore, the defining factor of a

truly private insurance plan, one between insured and an insurer, is lacking. *See W. Heritage Ins. Co*., 2016 U.S. App. LEXIS 14509 at *11.

36. In sum, MAOs are more akin to traditional Medicare, rather than a private health insurance plan. *Id*. at *16-17 ("There is no such thing as a [M]edicare Advantage insurance policy."). Medicare Advantage is, instead, a federal program. *Id*.

Medicare Part D

37. Medicare Part D coverage is a voluntary prescription drug benefit program for Medicare beneficiaries established in 2003. A beneficiary may enroll in Part D if he or she lives in the service area of a Part D plan and is entitled to Medicare benefits under Part A or enrolled under Part B.

38. Unlike Parts A and B, yet similar to Medicare Part C, Medicare Part D is based on a private market model, wherein Medicare contracts with private entities, known as Part D "sponsors" to administer prescription drug plans.

39. The Part D plan sponsor must provide qualified prescription drug coverage which includes "standard prescription drug coverage" or "alternative prescription drug coverage" with at least actuarially equivalent benefits.

40. A Plan D plan sponsor submits a bid in the year prior to the calendar year in which Part D benefits will actually be delivered. The bid contains a per member per month cost estimate for providing Part D benefits to an average Medicare beneficiary in the geographic area.

41. If the Plan D plan sponsor's bid exceeds the benchmark, the enrolled beneficiary must pay the difference as part of a monthly premium. CMS then provides each Part D plan sponsor with advance monthly payments equal to the Part D plan sponsor's standardized bid.

42. A Medicare Part C plan is not automatically enrolled to be a Medicare Part D plan sponsor, however, a vast majority of Medicare Par C plans include Medicare Part D services. *See* CMS, https://www.cms.gov/Outreach-and Education/Outreach/Partnerships/Downloads/nationalconversation.pdf (last visited March 20, 2018).

43. Medicare Part D is a voluntary prescription drug program for the elderly that increases monthly payments. *See* CMS, https://www.medicare.gov/sign-up-change-plans/get-drug-coverage/get-drug-coverage.html (last visited March 20, 2018).

Medicare Part D Payment Submission Process

44. Part D plan sponsors subcontract with many entities to provide drugs to the Medicare Part D beneficiaries enrolled in their plans, including pharmacy benefit managers (PBMs) who provide drugs through mail order and retail pharmacies.

45. When a pharmacy dispenses drugs to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the plan sponsor for the costs not paid by the beneficiary.

46. The Part D plan sponsor then notifies CMS that a drug has been purchased and dispensed through a document called a Prescription Drug Event ("PDE") record, which includes the amount paid to the pharmacy.

47. The PDE is an electronically created document that includes at least thirty-seven fields about a specific drug transaction.

48. As a condition for receiving its monthly payment from CMS, a Part D plan sponsor must certify the accuracy, completeness and truthfulness of all data related to the payment, which

may include enrollment information, claims data, bid submission data, and any other data specified by CMS.

49. If the claims data has been generated by a subcontractor of a Part D plan sponsor, such as a PBM, that entity must "similarly certify" that the claims data it has generated is accurate, complete and truthful, and must acknowledge that it will be used to obtain federal reimbursement.

50. Part D plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse.

51. CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, including pharmacies and PBMs, contain language obligating the downstream entity to comply with all applicable federal laws, regulations, and CMS instructions, including the False Claims Act, 31 U.S.C. § 3729, *et al*. and the Anti-Kickback Statute, 42 U.S.C. §1320a-7b.

SUBSYS

52. Subsys is a proprietary, single-use product that rapidly delivers fentanyl, an opioid analgesic, for transmucosal absorption underneath the tongue. Fentanyl was recently scheduled as a Schedule I substance under the Controlled Substances Act. *See* https://www.deadiversion.usdoj.gov/fed_regs/rules/2018/fr0206_4.htm (last visited March 20, 2018). Subsys is manufactured and sold exclusively by Insys. Insys received limited approval for Subsys from the Food and Drug Administration ("FDA") in January 2012 and commercially launched Subsys in March 2012. The only FDA approved use for Subsys is to treat breakthrough cancer pain.

53. Subsys is offered in 100, 200, 400, 600, 800, 1,200 and 1,600 mcg dosages, but the FDA requires the prescriber to use the lowest possible dose that adequately treats a *patient's cancer*

symptoms through "titration," where the doctor initially prescribes 100 mcg and slowly increases to higher dosages at a specified schedule.

54. Subsys comes in a 30 spray unit package. An example pricing schedule from 2014 for a single 30 spray unit package by strength is set forth in the following chart:

Strength (mcg)	**Price Per 30 Unit Package**
100	$907
200	$1,276
400	$1,806
600	$2,343
800	$2,885
1200	$2,399
1600	$3,164

55. Due to the substantial risk for abuse, addiction and overdose, Subsys is in a class of drugs known as Transmucosal Immediate-Release Fentanyl ("TIRF"). Subsys and other TIRF drugs are available only through a restricted program required by the FDA called the Transmucosal Immediate-Release Fentanyl Risk Evaluation and Mitigation Strategy (the "TIRF REMS Access Program"). Under the TIRF REMS Access Program, outpatients, healthcare professionals who prescribe to outpatients, pharmacies, and distributors must enroll in the program, and must comply with its requirements.

56. Despite the limited indicated use of Subsys for breakthrough cancer pain, a very small percentage of prescribers in the U.S. are oncologists. The majority of prescribers are pain

specialists, although primary care physicians, neurologists, dentists and podiatrists also write Subsys prescriptions.

Schedule II Drugs

57. The drugs and other substances that are considered controlled substances under the Controlled Substances Act (the "CSA"), 21 U.S.C.A. § 801, *et seq.*, are divided into five schedules. Fentanyl was previously a Schedule II drug, which means that it has been found to have "a high potential for abuse," has a "currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions," and abuse of the drug "may lead to severe psychological or physical dependence."[2] Examples of Schedule II drugs other than fentanyl include morphine, codeine, opium, methadone, cocaine, and amphetamine. Because Subsys contains fentanyl, Subsys is a Schedule II drug.

58. The DEA is responsible for enforcing the CSA and ensuring that all controlled substance transactions take place within the "closed system" of distribution established by Congress.[3] Within this "closed system," all legitimate handlers of controlled substances – manufacturers, distributors, physicians, pharmacies, and researchers – must be registered with the DEA and maintain strict accounting for all distributions.[4] A prescription substance such as Subsys may be issued only by an individual who is authorized to prescribe controlled substances in the jurisdiction in which the individual is licensed to practice and registered with the DEA.[5] To be valid, a prescription for a controlled substance must be issued by a practitioner acting in the usual

[2] 21 U.S.C.A. § 812(b)(2).
[3] Practitioner's Manual, Drug Enforcement Administration, Section I *available at* https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section1.htm (last visited March 21, 2018).
[4] *Id.*
[5] 21 C.F.R. § 1306.03.

course of professional practice.[6] The manner of issuance of prescriptions for controlled substances is also strictly regulated: all prescriptions must be dated as of and signed on the day when issued; all prescriptions must bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name and address of the practitioner.[7] For drugs listed in Schedule II, a pharmacist may only dispense directly pursuant to a written prescription signed by the practitioner.[8] The refilling of a prescription for a Schedule II controlled substance is prohibited.[9]

59. On February 6, 2018, the DEA temporarily placed Fentanyl as a Schedule I drug until February 6, 2020.[10]

Schedule I Drugs

60. All drugs listed in Schedule I have no currently accepted medical use in treatment in the United States and therefore may not be prescribed, administered, or dispensed for medical use. [11]

61. Schedule I drugs have a lack of accepted safety for use under medical supervision, and a high potential for abuse, therefore they have been banned for prescribing in the United States.

The FDA Approval Process

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[6] 21 C.F.R. § 1306.04(a).
[7] 21 C.F.R. § 1306.05.
[8] 21 C.F.R. § 1306.11.
[9] 21 C.F.R. § 1306.12.
[10] Temporary Scheduling Order: Temporary Placement of Fentanyl-Related Substances in Schedule I, U.S. Drug Enforcement Administration, available at https://www.deadiversion.usdoj.gov/fed_regs/rules/2018/fr0206_4.htm (last visited March 21, 2018).
[11] Practitioner's Manual, Drug Enforcement Administration, Section II, available at https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section2.htm (last visited March 21, 2018).

62. To obtain permission to market a drug, the manufacturer must submit a New Drug Application (NDA) to the FDA. The contents of a marketing application vary somewhat depending on the type of application, but generally include:

a. Proposed labeling for the product, which includes proposed indications and how the product is to be administered;

b. Information about the components, physical characteristics, and/or chemistry of the product;

c. Information about how the product will be manufactured;

d. Marketing history of the product, if any; and

e. Information from all relevant laboratory, animal and clinical studies supporting the approval or clearance of the application.

63. The Food, Drug and Cosmetic Act (the "FDCA") protects the public from drugs that are not proven to be safe and effective. Under the FDCA, a company must specify each intended use of a drug in its application to the FDA. After the FDA approves the drug as safe and effective for a specified use, any promotion by the manufacturer for other uses – known as "off-label" uses – renders the product misbranded. The misbranding of any drug is prohibited by the FDCA. The FDA approval process ensures that pharmaceutical companies market their medications for uses that are proven to be safe and effective.

64. Dr. Margaret Hamburg, former Commissioner of the FDA, has said that "the 'off-label' promotion of drugs threatens public health and the role of the FDA, which has served our country well and has protected Americans from unsafe and ineffective drugs."[12]

[12] *Allergan Agrees to Plead Guilty and Pay $600 Million to Resolve Allegations of Off-Label Promotion of Botox®,* U.S. Dept. of Justice Press Release, Food and Drug Administration, Office of Criminal Investigations (Sept. 1, 2010), https://www.justice.gov/opa/pr/allergan-

65. In addition to formal marketing efforts, less conspicuous methods of promoting drugs for off-label uses are also recognized threats to public health. As Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services explained, "fraudulent marketing of drugs through off-label promotion or kickbacks to prescribers undermines the protections afforded by the drug approval process and medical decision-making."[13]

66. Insys submitted a NDA for Subsys to the FDA on March 4, 2011, pursuant to Section 505(b)(2) of the FDCA. The NDA provided for the use of Subsys for "the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their *underlying persistent cancer pain.*"[14] The FDA approved the application for Subsys for use as recommended in the labeling text. Specifically, the FDA approved indications and usage for Subsys[15] are the following:

> Subsys is an opioid agonist indicated for the management of *breakthrough pain in cancer patients* 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent *cancer* pain.
>
> Patients considered opioid tolerant are those who are taking, for one week or longer, around-the-clock medicine consisting of at least 60 mg of oral morphine per day, at least 25mcg of transdermal fentanyl per hour, at least 30 mg of oral oxycodone per day, at least 8 mg of oral hydromorphone per day, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking Subsys.
>
> Limitations of Use:
> - Not for use in opioid non-tolerant patients.

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agrees-plead-guilty-and-pay-600-million-resolve-allegations-label-promotion-botox (last visited March 21, 2018).

[13] *Id.*

[14] Subsys NDA Approval Letter, FDA, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202788s000ltr.pdf (last visited March 21, 2018).

[15] Subsys prescribing information, http://www.subsys.com/assets/subsys/client_files/files/PrescribingInfo.pdf (last visited March 21, 2018) (emphasis added).

- *Not for use in the management of acute or postoperative pain, including headache/migraine, dental pain, or in the emergency room*.
- As a part of the Transmucosal Immediate-Release Fentanyl (TIRF) REMS Access program, Subsys may be dispensed only to outpatients enrolled in the program [see Warnings and Precautions (5.7)]. For inpatient administration of Subsys (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.

The contraindications listed on the FDA approved Subsys label are the following:

- Opioid non-tolerant patients.
- Management of acute or postoperative pain including headache/migraine and dental pain, or in emergency department.
- Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment.
- Known or suspected gastrointestinal obstruction, including paralytic ileus.
- Known hypersensitivity to fentanyl, or components of Subsys.[16]

67. The Subsys label is required to have a clearly marked section warning patients of the risk of life-threatening respiratory depression, medication errors, and abuse potential, also known as a "black box warning."

68. Section 505-1 of the FDCA authorizes the FDA to require the submission of a risk evaluation and mitigation strategy (REMS) when necessary. The factors the FDA considers pursuant to Section 505-1(a)(1) when making this determination include the following:

a. The estimated size of the population likely to use the drug involved;

b. The seriousness of the disease or condition that is to be treated with the drug;

c. The expected benefit of the drug with respect to such disease or condition;

d. The expected or actual duration of treatment with the drug;

e. The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.

[16] *Id.*

69. The FDA determined that a REMS was necessary for Subsys to ensure the benefits of the drug outweigh the risks of misuse, abuse, addiction, overdose, and serious complications due to medication errors.[17] In reaching this determination, the FDA considered the following:

- The *estimated number of patients in the United States with breakthrough cancer pain* is betwe*en 1 to 2 million*. This estimate is based upon the number of patients with cancer in the US (American Cancer Society), the proportion of cancer patients with moderate to severe pain, and the proportion of cancer patients with breakthrough pain.

- *The patients for this product are cancer patients with* pain that cannot be adequately controlled using around-the-clock oral or transdermal opioids alone. Many of these patients have multiple concurrent complications of their underlying disease and therapy.

- The most serious of the known adverse events that are related to the use of fentanyl-containing products include death, respiratory depression, and CNS depression which occur primarily if the product is not used properly. In addition to the aforementioned risks, fentanyl sublingual spray, as other fentanyl-containing products, can have a potential to increase intracranial pressure and induce bradyarrhythmias.[18]

70. As one element of the REMS, the FDA determined that Insys was required to distribute a Medication Guide to patients taking the drug because "Subsys poses a serious and significant public health concern requiring the distribution of a Medication Guide."[19]

71. The FDA also determined that Subsys could be approved "only if elements necessary to assure safe use are required as part of a REMS to mitigate the risks of misuse, abuse, addiction, overdose, and serious complications due to medication errors that are listed on the

[17] Subsys NDA Approval Letter, FDA, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202788s000ltr.pdf (last visited March 21, 2018docs

[18] Risk Evaluation and Mitigation Strategy (REMS) Memorandum, FDA, Center for Drug Evaluation and Research (Jan. 2, 2011), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202788Orig1s000RiskR.pdf (last visited March 21, 2018).

[19] *Id.*

labeling" pursuant to section 505-1(f)(1) of FDCA.[20] The FDA stated that "the elements to assure safe use will help assure proper patient selection and dispensing of Subsys."[21]

72. The TIRF REMS Access Program governs the health care industry's access to TIRF medications. The Program is arranged to ensure informed risk-benefit decisions before initiating treatment and ensure the proper use of TIRF medicines. The TIRF REMS Access Program requires all prescribers, pharmacies, wholesalers, and distributors to enroll in the program before prescribing, purchasing, or dispensing the TIRF medicines. All physicians who seek to prescribe TIRF substances to outpatients must first enroll in the TIRF REMS Access Program. Unless a physician enrolls in this Program, an authorized pharmacy may not fill prescriptions for TIRF medications written by a non-enrolled physician. Furthermore, before a patient can be prescribed a TIRF medicine, he or she must complete and sign a "Patient-Prescriber Agreement Form"[22] along with the prescribing physician. Each of these requirements must be renewed and completed every two years.

73. To enroll in the TIRF REMS Access Program, both prescribers and pharmacies must complete a TIRF REMS Education Program and correctly answer questions concerning the proper indications and dosage for the TIRF medicines. This Education Program relays key safety information essential for minimizing the risks associated with TIRF medicines and makes clear that TIRF medicines are only indicated for the management of breakthrough cancer pain in adult patients with cancer "who are already receiving and who are tolerant to regular opioid therapy for underlying persistent cancer pain."[23] Because life-threatening respiratory depression and death

[20] Subsys NDA Approval Letter, 3.
[21] *Id.*
[22] TIRF REMS Access Patient-Prescriber Agreement Form, available at https://www.tirfremsaccess.com/TirfUI/rems/pdf/ppaf-form.pdf (last visited March 21, 2018).
[23] Education Program for Prescribers and Pharmacists, TIRF REMS Access, 3, available at

could occur at any dose in patients not taking chronic opioids, TIRF medicines have strict contraindications for opioid non-tolerant patients.

74. Once the patient signs the Patient-Prescriber Agreement, the patient must take the prescription for a TIRF medicine to an enrolled pharmacy. The pharmacy will then enroll the patient in the TIRF REMS Access Program. Prescriptions written by prescribers who are not enrolled in the REMS program will not be authorized by the TIRF REMS Access Program, and TIRF medicines will not be dispensed to an outpatient who is not enrolled.

75. All pharmacies are required to be enrolled in the TIRF REMS Access Program, complete the TIRF REMS Education Program, and verify patient and prescriber enrollment when processing prescriptions.

76. All TIRF prescriptions must go through an electronic verification system via the pharmacy management system. When a prescription is denied, an appropriately coded message will be displayed on the pharmacy management system. Each day, wholesalers receive a list of enrollees in the TIRF REMS Access Program- including prescribers, pharmacies, and patients. If the prescriber, pharmacy, or patient is not enrolled in the program, the claim will not go through.

77. The goals of the TIRF REMS Access Program are to mitigate the risk of misuse, abuse, addiction, overdose, and serious complications due to medication errors by prescribing and dispensing TIRF medicines only to appropriate patients, which includes use only in opioid-tolerant patients; preventing inappropriate conversion between fentanyl products; preventing accidental exposure to children and others for whom it was not prescribed; and educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose.

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https://www.tirfremsaccess.com/TirfUI/rems/pdf/education-and-ka.pdf (last visited March 21, 2018).

78. This system failed because prescribers enrolled in the TIRF REMS Access Program, understanding that only cancer patients should be prescribed Subsys and should be prescribed the lowest dose initially, prescribed Subsys to patients without cancer diagnoses, some with higher initial doses than required, and inappropriately enrolled them in the TIRF REMS Access Program.

79. Pharmacists enrolled in the program should have also understood that only cancer patients should be prescribed Subsys and should be prescribed the lowest dose initially.

Plaintiff's Payments for Subsys Prescriptions

80. Plaintiff's Assignors offer prescription drug benefits pursuant to Medicare Part D.

81. Consistent with the TIRF REMS Access Program, and the closely-circumscribed approved uses of Subsys, Plaintiff's Assignors only provide payment and/or reimbursement for the FDA-approved use. The patient must receive prior authorization before his or her prescription for Subsys may be filled to ensure that Subsys is not being prescribed to the wrong patient for the wrong condition.

82. Insys knew of these prior authorization requirements.

83. Payers like Plaintiff's Assignors had procedures in place to enable them to screen for and deny reimbursement for improper and off-label uses of TIRF drugs like Subsys. In November 2012, payers, like Plaintiff's Assignors, only approved between 22-30 percent of prescriptions for Subsys.

Insys' Fraudulent Practices

84. In addition to the prior authorization requirements, Insys faced other impediments to the success of Subsys due to its limited approved use, including: its extremely narrow customer base; having to construct a sales and marketing force from the ground up; being a latecomer to a

mature market dominated by larger drug companies; having to comply with the FDA's stringent marketing restrictions; and needing to obtain approval of public and private resources of reimbursement, including health insurers, to subsidize the drug's very high price.

85. Despite these obstacles, Subsys widely exceeded market expectations. Since late 2014, Subsys has been the most prescribed TIRF product with 48% market share on a prescription basis.[24]

86. Behind that success is the secret, aggressive, fraudulent, and unlawful off-label marketing to prescribers who did not treat many cancer patients, payment of fees to speakers to promote Subsys off-label, providing monetary and non-monetary items (such as meals, jobs for family members, and expensive outings) to physicians in exchange for prescribing Subsys, and the payment of higher commissions to Insys sales representatives for selling higher doses of Subsys. Insys systematically engaged or negligently allowed its employees and/or agents to engage in deceptive sales and marketing practices which caused Plaintiff's Assignors to pay for Subsys to treat a variety of claimed illnesses and symptoms and at dosages for which Subsys had not received FDA approval and for which the drug was not safe or medically appropriate. Insys' deceptive conduct targeted Plaintiff's Assignors and other payers.

87. Insys and the Unnamed Co-Conspirators engaged in a scheme of deceptive marketing and sales practices which included: (1) directly marketing to and soliciting prescribers to prescribe Subsys for a variety of unapproved off-label uses; (2) misrepresenting the safety and medical efficacy of Subsys for off-label uses; (3) defrauding payers by disguising the identity and location of certain of Insys' employees who were obtaining approval for Subsys prescriptions; (4)

[24] Investors overview, Insys, *available* at http://investors.insysrx.com/phoenix.zhtml?c=115949&p=irol-irhome (last visited March 21, 2018).

instructing, scripting and coaching certain Insys employees to lie or mislead about patient diagnoses, the type of pain being treated, and the patient's course of treatment with other medication; (5) improperly and secretly compensating physicians for prescribing Subsys for off-label uses; (6) causing doctors to submit claim forms to Plaintiff's Assignors containing misinformation and omissions regarding Subsys; and (7) encouraging doctors to prescribe Subsys at higher dosages than necessary or appropriate.

88. These deceptive practices caused Plaintiff's Assignors to pay for Subsys claims to treat a variety of off-label conditions for which the drug was not properly the subject of covered reimbursement and was neither safe nor medically appropriate.

The Subsys Scheme

89. Even though Subsys was Insys' only product during the relevant time period, Insys' valuation soared. Insys turned Subsys into a billion dollar drug by (1) paying bribes and kickbacks to providers so they would prescribe Subsys off-label; (2) training Insys staff to pose as providers and call health insurance providers, like Plaintiff's Assignors, to make knowingly false representations about patient medical records; (3) encouraging Insys staff to execute fraudulent and deceptive tactics designed to trick Plaintiff's Assignors into paying for off-label prescriptions of Subsys; and (4) inducing prescribers to provide their patient medical charts to facilitate Insys' scheme and induce payment from third party payers, including Plaintiff's Assignors.

90. Insys senior executives concocted a two-pronged fraudulent scheme to avoid the obstacles to selling more Subsys. This scheme sent Insys' revenues soaring into the hundreds of millions of dollars annually at the expense of payers like Plaintiff's Assignors. This scheme was concocted to overcome Insys' twin revenue problems: (1) that Subsys was only approved for the

one to two million cancer patients with breakthrough pain and (2) that insurers had procedures in place to avoid paying for improper off-label uses of Subsys.

91. The two-pronged fraudulent scheme that Insys developed involved a multi-faceted, complex, and hugely profitable effort to defraud and induce Plaintiff's Assignors into reimbursing wrongly-prescribed Subsys through (1) paying bribes and kickback to providers so they would prescribe Subsys off-label; (2) marketing Subsys for off-label use and misrepresenting the efficacy (3) training Insys staff to pose as providers' staff and call third party payers to make knowingly false misrepresentations and omit material information about patient medical records, (3) encouraging Insys staff to execute fraudulent and deceptive tactics designed to trick or mislead third party payers into paying for higher doses and off-label prescriptions of Subsy, and (4) inducing prescribers to provide confidential member information to facilitate Insys' scheme and to induce payment from third party payers.

92. In 2012, Insys developed a marketing program to increase the number of prescriptions of Subsys through a sham "speaker program."

93. Through this "speaker program," Insys paid the Un-Named Co-Conspirator physician prescribers to give presentations on Subsys, purportedly to increase brand awareness via peer-to-peer educational lunches and dinners.

94. Most of the presentations, however, would make only a cursory mention of Subsys, and in some there was no mention of Subsys at all. And many of the programs were attended by sales representatives or other individuals who had no authority to prescribe the drug.

95. The prescribers chosen for these lucrative speaking opportunities is further evidence of the true motivation behind the program. Insys targeted prescribers running pain clinics

– particularly those who were high-volume opioid prescribers – for these "speaker programs," as opposed to oncologists treating patients that met the conditions set forth in the label.

96. The top 10 prescribers of Subsys were paid handsomely for their participation in the speaker program – collectively receiving more than $870,000 in speaker fees in 2013 and 2014 alone.

97. As discussed in greater detail below, some of the practitioners on the top ten Subsys prescriber list have been criminally convicted of accepting kickbacks.

98. Insys' efforts to funnel illegal kickbacks to Subsys prescribers were not limited to speaker fees. The company also offered valuable administrative services to prescribers' offices at no charge in exchange for Subsys prescriptions. To that end, Insys created a "Reimbursement Unit" that was deployed to prescriber practices to handle the prior-authorization process. As discussed in greater detail below, these free services not only benefited the prescribers, but also allowed Insys to control the false messaging to insurers, including Plaintiff's Assignors.

99. In addition to the speaker program, Insys was engaged in a scheme to promote Subsys off-label by aggressively targeting high-volume opioid drug prescribers without regard to the suitability of the patient population for the approved use of Subsys.

100. Insys misrepresented to prescribers and patients the approved use and dosage parameters for Subsys.

101. Insys sales representatives encouraged prescribers to disregard FDA approved indications and FDA mandated dosing, instead marketing Subsys for breakthrough pain generically. After Insys secured a prescription for a patient, the Insys Reimbursement Center ("IRC") would call health plans or pharmacy benefit managers acting on behalf of health plans to

obtain prior authorizations, by means of misrepresenting their affiliation with doctor's offices and misrepresenting diagnoses stating the patient had cancer.

102. Plaintiff's Assignors suffered financial loss because of Insys and the Unnamed Co-Conspirators' scheme to defraud them into reimbursing money for unnecessary, unapproved, off-label prescriptions that would have never been approved but for Insys' course of fraudulent conduct.

Insys' "Reimbursement Unit"

103. Insys created a vehicle to ensure that the requisite lies would be conveyed to payers, like Plaintiff's Assignors, to obtain the prior authorizations necessary for coverage of the off-label Subsys prescriptions. Insys called this its "Reimbursement Unit" and operated it from approximately January 2013 through October 2016.

104. Employees in Insys' Reimbursement Unit would conceal or misrepresent their identities when seeking prior authorization for Subsys claims by informing Plaintiff's Assignors that they were calling from the prescriber's office. Plaintiff's Assignors reasonably relied on these misrepresentations.

105. Additionally, Insys blocked access to the Reimbursement Unit's phone number in order to hide the geographical location from which Reimbursement Unit employees were calling. This was done for the sole purpose of preventing Plaintiff's Assignors from figuring out that the calls were being made from a different location than the prescriber's offices.

Misrepresentations During the Prior Authorization Process

106. Because Insys understood that insurers would not authorize payment for non-indicated uses of Subsys, to obtain prior authorizations, Insys employees calling in prior

authorization requests would represent to Plaintiff's Assignors that the patient had a cancer diagnosis and was tolerant to opioids even when that was not the case.

107. Specifically, according to criminal complaints filed against Insys executives and managerial employees, during the prior authorization process, Insys employees were directed to represent that the patients for whom prior authorizations were being sought had cancer even when they did not. Insys employees were trained to answer prior authorization questions using a script, sometimes called "the spiel" to mislead health insurers, including Plaintiff's Assignors.

108. The "spiel" read: "The physician is aware that the medication is intended for the management of *breakthrough pain in cancer patients*. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable)."

109. The script deliberately omitted the word "cancer."

110. According to the criminal complaints, Insys employees were also directed to fraudulently assert that a patient had a cancer diagnosis regardless of the patient's history and regardless of whether the prescriber had prescribed Subsys for a different diagnosis.

111. Similarly, Insys employees were directed to falsely confirm lists of tried and failed medications that would qualify the patient to receive Subsys.

Government Investigations and Actions

112. Insys and the Unnamed Co-Conspirators' wrongful scheme has drawn numerous governmental actions and investigations.

113. The United States commenced a criminal action against Unnamed Co-Conspirators Babich, Burlakoff, Gurry, Simon, Lee and Rowan, who were arrested on December 8, 2016 on charges they led a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe Subsys and defraud healthcare payers. *U.S. v. Babich, et al.*, No. 1:16-cr-10343 (D. Mass.). The

indictment alleges that practitioners wrote large numbers of prescriptions for Subsys in exchange for bribes and kickbacks and that the former executives conspired to mislead and defraud health insurance providers who would not approve payment for the drug when it was prescribed for non-cancer patients.

114. The United States also commenced a criminal action against a former manager at Insys, Elizabeth Gurrieri, who pled guilty on June 19, 2017. *U.S. v. Gurrieri*, No. 1:17-cr-10083 (D. Mass.). Gurrieri admitted that she helped lead the nationwide scheme to defraud insurance companies by directing employees at the Insys Reimbursement Center to lie to insurers, defrauding them into paying for Subsys. Gurrieri admitted that she and her co-conspirators used a call center to contact insurance companies to provide prior authorizations, often under false pretenses for patients not suffering from cancer. Insys employees sometimes disguised where they were calling from, leading payers to believe that they were speaking directly with a doctor's office, rather than with the drug maker that stood to profit.

115. U.S. Senator Claire McCaskill, Ranking Member of the U.S. Senate Committee on Homeland Security and Governmental Affairs ("HSGAC"), led an investigation into the soaring rate of opioid deaths in the United States and sent letters to five major opioid manufacturers, including Insys, requesting documents related to the sales, marketing, and educational strategies employed to promote opioid use on March 28, 2017. The HSGAC released its report on Insys on September 6, 2017, entitlted "Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization."[25] The report revealed an internal Insys presentation dated 2012 and entitled "2013 SUBSYS Brand Plan," where Insys identified one of six "key strategic

[25] Exhibit A.

imperatives" as "Mitigate Prior Authorization barriers."[26] The HSGAC reported an internal Insys document that showed that Insys lacked even basic measures to prevent its employees from manipulating the prior authorization process and received clear notice of these deficiencies."[27] The HSGAC reviewed the case of Subsys patient Sarah Fuller, who died of allegedly improper and excessive Subsys use, and reported an audio recording that revealed that "an Insys employee misled representatives of Envision Pharmaceutical Services to obtain approval for her prescription."[28]

116. The Oregon Attorney General served a Notice of Unlawful Trade Practices on Insys on July 10, 2015, and on August 5, 2015, reached a $1.1 million settlement with Insys. Oregon was the first state in the country to allege that Insys promoted Subsys "off-label" for non-cancer pain, such as back and neck pain, uses for which Subsys is neither safe, approved, nor eligible for reimbursement by either public or private payers. Oregon outlined allegations in its Notice that Insys unconscionably targeted "problem doctors" who improperly prescribed opiates with aggressive Subsys promotion and that Insys facilitated prescribing of Subsys for contraindicated uses.

117. The New Hampshire Attorney General brought an enforcement action under the state's Consumer Protection Act against Insys. On or about December 8, 2015, New Hampshire issued a subpoena to Insys for an investigation into the commercial practices of Insys regarding marketing of Subsys in New Hampshire. On January 18, 2016, New Hampshire's Attorney General accepted the Assurance of Discontinuance, under which Insys has paid the State of New Hampshire $2,900,000 for its collective violations of the state's Consumer Protection Act. Insys

[26] *Id.* at 5.
[27] *Id.* at 1.
[28] *Id.* at 1-2.

also agreed to make a direct payment of $500,000 to the New Hampshire Charitable Foundation to be used to prevent or remediate problems related to abuse, misuse, or mis-prescribing of opioid drugs in New Hampshire.

118. The Illinois Attorney General filed a state consumer fraud complaint on August 25, 2016, seeking to enjoin Insys from doing business in the state for its off-label promotion of Subsys. *Illinois v. Insys Therapeutics, Inc.*, No. 2016-CH-11216 (Cook Co.). Illinois also sought a declaration that Insys violated Section 2 of the Illinois Consumer Fraud Act by engaging in unlawful acts and practices and an injunction preventing Insys from engaging in unfair and/or deceptive sales practices. *See* 815 Ill. Comp. Stat. 505/2. On August 18, 2017, Illinois announced a settlement of $4.5 million with Insys. The settlement requires Insys to comply with the Illinois Consumer Fraud Act, the Illinois and federal Food, Drug, and Cosmetics Acts, and the AKS.[29]

119. The Arizona Attorney General filed an Arizona Consumer Fraud lawsuit against Insys, Alec Burlakoff, Elizabeth Gurrieri, and three Arizona doctors, including Steve Fanto, on August 31, 2017.[30] Arizona alleges that Insys engaged in a fraudulent marketing scheme designed to increase the sales of Subsys and violated the Arizona Consumer Fraud Act by providing insurers with false and misleading information to obtain prior authorization for Subsys prescriptions for patients. Arizona alleges that Insys employees were instructed to mislead insurers into believing that patients who were prescribed Subsys had cancer, when in fact they did not. Arizona alleges that the three doctors collected sham educational "speaker fees" in exchange for writing prescriptions for Subsys. Arizona alleges that more than $33 million, or 64 percent, of Subsys

[29] *Madigan Reaches $4.5 [Million] Settlement With Drugmaker Insys for Deceptively Selling & Marketing Highly Addictive Opioid Painkiller*, Illinois Attorney General (Aug. 18, 2017), http://www.illinoisattorneygeneral.gov/pressroom/2017_08/20170818.html (last visited March 22, 2018).

[30] *Arizona v. Insys Therapeutics, et. Al.* (Ariz. Sup. Ct., Maricopa Co.)

sales in Arizona came from prescriptions written by the three doctors between March 2012 to April 2017. This litigation is ongoing.

Criminal Indictments, Pleas and Convictions

120. In December 2016, several of Insys' executives and managers were indicted for, *inter alia*, conspiracy to mislead and defraud health insurance providers who were reluctant to approve payment for the drug when prescribed for non-cancer patients.

121. According to the indictment, Insys achieved its goal of increasing prescriptions by setting up its "reimbursement unit," which was dedicated to obtaining prior authorization directly from insurers and pharmacy benefit managers.

122. Among other things, the executives were charged with conspiracy to commit racketeering, conspiracy to commit wire and mail fraud, and violations of RICO.

123. Additionally, in February 2016, a former Insys sales manager, Natalie Reed Perhacs, pled guilty to conspiracy to commit healthcare fraud including engaging in kickback schemes.

124. In the plea, Perhacs admitted that she was hired to be the personal sales representative for one of Insys' most important prescribers, Dr. Xiulu Ruan.

125. Perhacs admitted that her primary responsibility at Insys was to increase the volume of Subsys prescribed by Dr. Ruan, and his partner, Dr. John Patrick Couch. This was accomplished by: (1) handling prior authorizations for their patients who had been prescribed Subsys; (2) identifying patients who had been at the same strength of Subsys for several months and recommending that Dr. Ruan or Dr. Couch increase the patients' prescription strength; and (3) setting up and attending paid speaker programs.

126. Perhacs admitted that because of her involvement in the prior authorization process, she knew that the vast majority of Dr. Ruan and Dr. Couch's patients did not have breakthrough cancer pain.

127. Perhacs admitted that she was also responsible for setting up and attending speaker programs for Dr. Ruan and Dr. Couch. Perhacs scheduled approximately one speaker program per doctor per week. For a majority of the speaker programs, Dr. Ruan and Dr. Couch either (1) repeatedly spoke to the same prescribers about Subsys, (2) spoke to just their staff about Subsys, or (3) did not speak about Subsys.

128. Perhacs admitted that the purpose of the speaker program was not to promote Subsys, but to funnel kickbacks to high-volume Subsys prescribers.

129. Perhacs admitted that she was provided strong financial incentives to get Dr. Ruan and Dr. Couch to prescribe Subsys. Commissions from off-label prescriptions written by Dr. Ruan and Dr. Couch resulted in Perhacs making over $700,000 between April 2013 and May 2015, when Dr. Ruan and Dr. Couch were arrested.

130. On May 20, 2015, Drs. Ruan and Couch were indicted for (1) conspiracy to distribute controlled substances outside the usual course of professional practice and not for a legitimate medical purpose, and (2) conspiracy to commit healthcare fraud.

131. Dr. Couch and Dr. Ruan were accused of running a pill mill and prescribing controlled substances, including Subsys, that they were paid to promote.

132. According to the indictment, one of the objectives of their conspiracy to commit healthcare fraud was the unlawful payment to and receipt of illegal kickbacks as an inducement and in exchange for their prescribing of Subsys.

133. Between August 2012 and May 2015, Insys allegedly paid Dr. Ruan and Dr. Couch a combined total in excess of $115,000 for sham "speaker fees."

134. Between April 2012 and May 2015, Dr. Ruan and Dr. Couch were alleged to have written thousands of prescriptions for Subsys, nearly all of which went to patients who did not have cancer.

135. By early 2013, Dr. Ruan and Dr. Couch had become two of the top ten largest volume prescribers of Subsys nationwide.

136. Those doctors were subsequently accused of killing four patients.

137. The federal trial of Dr. Ruan and Dr. Couch began on January 5, 2017.

138. On February 23, 2017, Dr. Ruan and Dr. Couch were found guilty of, among other things, RICO conspiracy, conspiracy to commit health care fraud, conspiracy to violate the Anti-Kickback statute, and wire and mail fraud conspiracy.

139. Similarly, in June 2015, Heather Alfonso, an advanced practice registered nurse pled guilty to accepting $83,000 in kickbacks from Insys.

140. As part of her plea, Alfonso admitted that she prescribed Subsys to patients who did not have a cancer diagnosis. However, prior authorizations submitted by her on behalf of these patients represented that they had cancer.

141. Alfonso also admitted that she was paid $1,000 per speaking engagement under Insys' sham "speaker program." In the majority of instances, the only attendees at those programs were individuals who had no license to prescribe controlled substances, such as medical assistants, receptionists, friends or co-workers. Further, at the majority of those programs, Alfonso did not give any presentation about Subsys.

142. Alfonso admitted that the "speaker program" influenced her to increase the number of Subsys prescriptions she wrote, which she accomplished in part by finding more patients for whom she could prescribe the drugs.

143. On February 1, 2017 a Rhode Island Grand Jury returned an indictment for Dr. Jerrold Rosenberg, amongst the charges against Rosenberg were multiple counts of health care fraud. Subsys was specifically mentioned in the indictment as a "Fentanyl Spray". While Insys and other former executives were not specifically mentioned due to ongoing investigations, the scheme is the same as mentioned above.

144. On October 20, 2017, Rosenberg accepted a plea agreement wherein he pled guilty to health care fraud and conspiracy to receive kickbacks in exchange for arranging the ordering of goods and items for which payment was made by a federal health care program.

145. Rosenberg was sentenced to 51 months of prison in connection with the Insys scheme.

146. On May 2, 2014, a criminal complaint was filed against Dr. Gavin Awerbuch of West Bloomfield, Michigan. As of May 2, 2014, Awerbuch caused the submission of more Medicare claims for Subsys than anyone in the country. Awerbuch caused $6,969,100.33 worth of prescriptions of Subsys to be prescribed to Medicare beneficiaries, the next closest individual was a Texas resident who caused $1,615,254.04 in Subsys prescriptions.

147. Amongst the charges against Awerbuch were health care fraud and aiding and abetting the distribution of controlled substances. Awerbuch pled guilty to both counts.

148. On March 15, 2018, Gordon Freedman, Jeffrey Goldstein, Todd Schlifstein, Dialecti Voudouris and Alexandru Burducea, all doctors in New York, were indicted by a grand

jury on conspiracy to violate the Anti-Kickback Statute, amongst other violations, stemming from their connection to Insys specifically due to the pharmaceutical Subsys.

149. The case of Freedman, Goldstein, Schlifstein, Voudouris and Burducea is ongoing.

150. The above referenced cases are just exemplars of the ongoing scheme that Insys perpetrated across the country in almost every state and locality.

Class Allegations

151. Plaintiff brings this action, pursuant to Federal Rule of Civil Procedure 23, on behalf of itself and the following classes:

> **Class 1**: All Medicare Advantage Organizations and related entities in the United States and its territories who purchased, paid, provided reimbursement, and/or possess the recovery rights to reimbursement, for some or all of the purchase price of Defendant's Subsys prescribed to individuals without a cancer diagnosis pursuant to Medicare Part C and D contracts offering Medicare Part D services from January 2012, to present. This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (b) all federal and state governmental entities except for cities, towns, or municipalities with self-funded prescription drug plans; and (c) any judges or justices involved in this action and any members of their immediate families.

> **Class 2:** All MAO, MA-PD, or PDP sponsors and related entities in the United States and its territories who purchased, paid, provided reimbursement, and/or possess the recovery rights to reimbursement, for some or all of the purchase price of Defendant's Subsys prescribed to individuals without a cancer diagnosis pursuant to Medicare Part D contracts providing services from January 2012 to present. This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (b) all federal and state governmental entities except for cities, towns, or municipalities with self-funded prescription drug plans; and (c) any judges or justices involved in this action and any members of their immediate families.

152. Plaintiff brings this action both individually and on behalf of (a) national injunctive

class and/or (b) a national damages class.

153. As discussed in this Class Action Complaint, Defendant and the Unnamed Co-Conspirators have enjoyed ill-gotten gains from the sales of Subsys at the expense of third-party payer health coverage providers and Class Members suffering damages to their property and business. Such damages apply to all individual Class Members and Plaintiff. Class action law has long recognized that, when a company engages in conduct that has uniformly harmed a large number of claimants such as Plaintiff, other third-party payors, and consumers, class resolution is an effective tool to redress the harm.

154. Here, Plaintiff and the Class Members have been deprived of property and money by being caused to purchase prescriptions of Subsys at unlawfully high prices and volumes as a direct result of Defendant and the Unnamed Co-Conspirators engaging in racketeering activity as alleged throughout this Complaint.

155. The Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy:

a. Numerosity: There are hundreds of entities (including the organizations that assigned their rights to Plaintiffs) throughout the United States, including Ohio, that were forced to pay for Subsys on behalf of beneficiaries without a cancer diagnosis. Thus, the numerosity element for class certification is met.

b. Commonality: Questions of law or fact are common to all members of the Class. Defendant's and the Unnamed Co-Conspirators illegal pattern of racketeering activity and unlawful conduct having a common, adverse effect on all purchasers of Subsys, specifically, Plaintiff's Assignors, who were left without an option but to pay Defendant's illegally obtained prescriptions due to Defendant's unlawful

scheme. Therefore, common questions of law or fact are prevalent throughout the class, i.e., whether Defendant and the Unnamed Co-Conspirators engaged in a pattern of racketeering activity and conspired to provoke Plaintiff's Assignors and the Class into paying for illegally prescribed Subsys. Each Class Member shares the same needed remedy, i.e., reimbursement for unlawfully paid bills and lost money due to the Defendant and the Unnamed Co-Conspirators' racketeering activity, disgorgement of the Defendant's profits from the illegal venture, and imposition of injunctive and equitable relief to stop Defendant from continuing in their activities.

c. Typicality: Plaintiff's claims are typical of the claims of the Class because their claims arise from the same course of conduct by Defendant and the Unnamed Co-Conspirators, i.e., fraud and racketeering activity. Plaintiff's Assignors paid or reimbursed for prescriptions of Subsys where they would have not submitted payment as a consequence of Defendant's and the Unnamed Co-Conspirators pattern of racketeering activity. Plaintiff's claims are, therefore, typical of the Class.

d. Adequacy: Plaintiff will fairly and adequately represent and protect the interests of the Class. Its interests in vindicating these claims are shared with all members of the Class. In addition, Plaintiff is represented by competent and experienced counsel in class action litigation.

156. The Class is properly brought and should be maintained as a class action under Rule 23(b) because a class action in this context is superior. Pursuant to Rule 23(b)(3), common issues of law and fact predominate over any questions affecting only individual members of the Class. Defendant and the Unnamed Co-Conspirators deliberately conspired to sell Subsys for uses would have not been paid but for Defendant and the Unnamed Co-Conspirators engaging in a pattern of racketeering activity, thus depriving Plaintiff''s Assignors and the Class of funds used to pay for

the unlawful prescriptions.

157. Plaintiff alleges that it and the Class would have paid nothing for Subsys prescribed to patients without cancer if Defendant and the Unnamed Co-Conspirators had not engaged in racketeering conduct.

CLAIMS FOR RELIEF

COUNT I: VIOLATIONS OF 18 U.S.C. §1962(C) OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. §1961, *ET SEQ.*

158. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

159. Defendant is a "person," pursuant to 18 U.S.C. § 1961(3), who conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c).

160. Each Plaintiff and Class Member is a "person," pursuant to 18 U.S.C. § 1961(3), who was injured in its business or property as a result of Defendant's and the Unnamed Co-Conspirators wrongful conduct.

161. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c).

162. As explained in detail below, Defendant and the Unnamed Co-Conspirators sought to increase Subsys prescriptions by defrauding health insurers across the country through a fraudulent scheme designed to secure greater profits and market share and extract ill-gotten gains from Plaintiff's Assignors and the Class. As explained in detail throughout this Complaint,

Defendant's misconduct violated Sections 1962(c) and (d) of RICO and caused damage to Plaintiff and the Class.

A. Description of the Defendant's RICO Enterprise.

163. RICO defines an enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). An association-in-fact enterprise requires three structural features: (1) a purpose; (2) relationships among those associated with the enterprise; and (3) longevity sufficient to permit those associates to pursue the enterprise's purpose.

164. The RICO Enterprise is comprised of Insys Therapeutics Inc., its directors and executives, former directors and executives including Michael L. Babich, John N. Kapoor, Alec Burlakoff, and Michael J. Gurry, salespersons, former salespersons including Richard M. Simon, Sunrise Lee, and Joseph A. Rowan, members of Insys Therapeutics' IRC, former members of Insys Therapeutics' IRC, doctors who have received kickbacks in exchange for prescribing Subsys and for recruiting other physicians to prescribe Subsys through speaker programs or kickbacks, including un-named co-conspirator physicians, and entities that conspired in the carrying out of the enterprise such as pharmacies, information technology contractors that set up phone systems to mask numbers associated with contacting health plans or PBMs regarding fraudulent pre-authorization forms.

165. The Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendant and the Unnamed Co-Conspirators as set forth above. All entities are persons within the meaning of 18 U.S.C. § 1961(3) and acted to enable Defendant and the Unnamed Co-Conspirators to fraudulently market and sell Subsys to Plaintiff's Assignors and the Class.

166. The Enterprise functioned as an ongoing organization and continuing unit. The Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Each of these Enterprise participants, including Defendant, is a "person" distinct from the Enterprise.

167. Defendant, in concert with the other Enterprise participants, created and maintained systematic links for a common purpose, i.e., to aid in the marketing and the sale of Subsys for off-label prescription uses, while suppressing evidence and information to the contrary. Each of the participants in the Enterprise received substantial revenue from the scheme to promote Subsys as safe and effective for patients that did not meet the standards for receiving such prescription. Such revenue was exponentially greater than it would have been if Subsys was marketed appropriately and the true efficacy and safety risks of Subsys were disclosed to the patients who were prescribed Subsys when they otherwise should not have been. All participants of the Enterprise were aware of Defendant's control over the activities of the Enterprise in promoting Subsys. Furthermore, each portion of the enterprise benefited from the existence of the other parts.

168. Defendant established the Enterprise to accomplish goals that were instrumental to its scheme to market Subsys for off-label uses as set forth above.

169. There was a common strategy employed by Defendant and the Unnamed Co-Conspirators, whereby the Enterprise would recruit and use physicians to improperly prescribe Subsys and to foster the fraudulent scheme to obtain prior authorization and payment for medically improper, "off-label" Subsys prescriptions.

170. As part of this common strategy, Defendant paid kickbacks, such as speaker fees, to prescribers who wrote Subsys prescriptions.

171. In furtherance of the scheme, Defendant and the Unnamed Co-Conspirators affirmatively misrepresented or concealed the "off-label" use for which Subsys was prescribed and

the medical history of the patient to whom it was prescribed as well as the existence, amount, and purpose of the kickbacks given to prescribers. Specifically, Defendant claimed that the kickbacks paid to prescribers were for the speaking engagements when, in fact, they were *quid pro quo* payments for writing Subsys prescriptions.

172. The common fraudulent purpose of the Enterprise was effectuated through the broad network consisting of Insys and the other Enterprise participants.

173. Defendant, through its illegal enterprise, engaged in a pattern of racketeering activity, which involved a fraudulent scheme to obtain coverage for Subsys prescriptions that were improperly prescribed.

174. Defendant engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across state boundaries, such as the marketing, promotion, advertisement, distribution, and sale of Subsys throughout the country, and the receipt of monies from the sale of the same.

B. Predicate Acts: Mail and Wire Fraud.

175. To carry out, or attempt to carry out, the scheme to defraud, Defendant did knowingly conduct or participate, directly or indirectly, in the affairs of the Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

176. Specifically, Defendant has committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years.

177. The multiple acts of racketeering activity which Defendant committed, or aided or

abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the Defendant's regular use of the facilities, services, distribution channels, and employees of the Enterprise. Defendant participated in the scheme to defraud by using mail, telephone, and the Internet to transmit mailings and wires in interstate or foreign commerce.

178. Defendant used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions.

179. In devising and executing the illegal scheme, Defendant devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiff's Assignors and the Class Members or to obtain money from Plaintiff's Assignors and the Class Members by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. To execute the illegal scheme, Defendant committed these racketeering acts intentionally and knowingly with the specific intent to advance the illegal scheme.

180. Defendant's predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

> (a) Mail Fraud: Defendant violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, price and/or sell Subsys by means of false pretenses, misrepresentations, promises, and omissions.
>
> (b) Wire Fraud: Defendant violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on false pretenses, misrepresentations, promises, and omissions.

181. Defendant's use of the mails and wires include, but are not limited to: (a) the transmission of claims and/or prior authorization materials relating to Subsys prescriptions for off-

label uses; (b) written, telephone, or electronic communications regarding and/or negotiating the kickback amount for prescribers who wrote Subsys prescriptions as described herein; (c) the use of the mails or wires to make the payments associated with the kickbacks paid to prescribers who wrote off-label Subsys prescriptions; (d) the use of the mails or wires to bill for and collect revenues and/or profits from the sale of off-label Subsys prescriptions; and (e) the transmission of marketing or other materials relating to Subsys.

182. During the relevant time period Defendant also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail with various other affiliates, regional offices, divisions, dealerships, and other third-party entities in furtherance of the scheme.

183. The mail and wire transmissions described herein were made in furtherance of Defendant's scheme and common course of conduct designed to obtain coverage for improperly written Subsys prescriptions and fraudulently extract money from Plaintiff's Assignors and the Class Members.

184. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden and cannot be alleged without access to Defendant's business records. However, Plaintiff has described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. These include thousands of communications to perpetuate and maintain the scheme, including the things and documents described above.

185. The Defendants have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), the Defendants conspired to violate 18 U.S.C. § 1962(c), as described herein. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, have participated as co-conspirators with the Defendants in these offenses and

have performed acts in furtherance of the conspiracy to increase or maintain revenues, increase market share, and/or minimize losses for the Defendants and their unnamed co-conspirators throughout the illegal scheme and common course of conduct.

186. Defendant aided and abetted others in the violations of the above laws.

187. To achieve its common goals, Defendant hid from Plaintiff's Assignors, insurers, health plans and the general public, the true use for which Subsys was being prescribed, the medical history of the patient to whom Subsys was prescribed and the kickbacks the prescribers were receiving for writing Subsys prescriptions.

188. Defendant and each member of the conspiracy, with knowledge and intent, agreed to the overall objectives of the conspiracy and participated in the common course of conduct. Indeed, for the conspiracy to succeed, Defendant and its Unnamed Co-Conspirators had to agree to conceal their fraudulent tactics.

189. As described herein, Defendant engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from Plaintiff's Assignors and the Class Members based on their misrepresentations and omissions. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

190. As a result of Defendant's conduct, and in particular, its pattern of racketeering activity, Plaintiff and the putative Class Members have been injured in their business and/or property in multiple ways, including but not limited to paying for prescriptions that were written contrary to the Plaintiff's Assignors' policies for coverage and contrary to the prescribed medication's indications.

191. By virtue of these violations of 18 U.S.C. § 1962(c), Defendant is liable to Plaintiff and the Class Members for three times the damages sustained, plus the costs of this suit, including reasonable attorney's fees.

192. By reason of the foregoing, and as a direct and proximate result of Defendant's fraudulent misrepresentations, Plaintiff and the Class have suffered damages. Plaintiff and the Class are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

COUNT II: VIOLATIONS OF 18 U.S.C. §1962(D) OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. §1961, *ET SEQ.*

193. Plaintiff incorporate by reference all preceding paragraphs as if fully set forth herein.

194. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

195. Defendant and the Unnamed Co-Conspirators violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy was to conduct or participate in, directly or indirectly, the conduct of the affairs of the Enterprise described previously through a pattern of racketeering activity. Defendant conspired with the Enterprise participants, *inter alia*, Insys directors and executives, sales representatives, members of the IRC teams, key opinion leader physicians receiving kickbacks for prescribing Subsys and for recruiting other physicians to prescribe Subsys, un-named co-conspirator physicians, un-named co-conspirator pharmacies, and other as of yet unknown entities that participated in the conspiracy, such as information technology contractors who set up systems masking numbers used to contact third party payers to promote and obtain payment for Subsys for off-label prescription use.

196. Defendant and the Unnamed Co-Conspirators, as co-conspirators, engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiff's Assignors and the Class of money.

197. The nature of the co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

198. As a direct and proximate result of Defendant's overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiff and the members of the Class have been and are continuing to be injured in their business or property as set forth more fully above.

199. Defendant sought to and has engaged in the commission of overt acts, including the following unlawful racketeering predicate acts discussed extensively herein, including but not limited to:

a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud violations of 18 U.S.C. §§ 1341 and 1346;

c. Multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and

d. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

200. Plaintiff and members of the Class have been injured in their property by reason of the violations of the above federal laws in that Plaintiff's Assignors and members of the Class

have paid millions of dollars for Subsys that they would not have paid had Defendant and the Unnamed Co-Conspirators not conspired to violate 18 U.S.C. § 1962(c).

201. Injuries suffered by Plaintiff and the Class were directly and proximately caused by Defendant's racketeering activity as described above. Had prescribers, patients, and third-party payers known the true nature of the off-label Subsys prescriptions and illegal marketing scheme Plaintiff's Assignors and the Class Members would not have allowed the claims to be reimbursed.

202. By virtue of these violations of 18 U.S.C. § 1962(d), Defendant is liable to Plaintiff and the Class for three times the damages Plaintiff and the Class members have sustained, plus the cost of this suit, including reasonable attorney's fees.

203. By reason of the foregoing, and as a direct and proximate result of Defendant's fraudulent scheme, Plaintiffs and the Class have suffered damages. Plaintiff and the Class are entitled to compensatory damages, punitive damages, costs and reasonable attorneys' fees.

COUNT III:COMMON LAW FRAUD

204. Plaintiff incorporate by reference all preceding paragraphs as if fully set forth herein.

205. As alleged extensively above, Defendant affirmatively misrepresented and/or concealed and suppressed material facts concerning: (a) the use for which Subsys was being prescribed; (b) the identity of the individuals seeking prior authorization from Plaintiff's Assignors and the Class Members for Subsys prescriptions; (c) the medical and treatment history of the patients receiving Subsys prescriptions; and (d) the kickbacks being paid to prescribers for writing Subsys prescriptions.

206. Defendant valued its profits over the trust, health and safety of the beneficiaries of Plaintiff's Assignors and the Class Members.

207. Necessarily, Defendant took steps to ensure that their employees and co-conspirators did not reveal the details of the Subsys scheme to Plaintiff's Assignors and Class Members.

208. Defendant's false representations and omissions were material to Plaintiff's Assignors and the Class Members.

209. Plaintiff and the Class Members reasonably relied on Defendant's deception, and Defendant intended that they would so rely. Plaintiff had no way of discerning that Defendant was, in fact, deceiving them because they possessed exclusive knowledge regarding the nature of the Subsys prescriptions and the patients for whom they were written; intentionally concealed the foregoing from, Plaintiff, the Class Members and the public; and made incomplete or negligent representations about the prescriptions and the Defendant's role in obtaining those prescriptions and the prior authorizations for those prescriptions, while purposefully withholding material facts from Plaintiff that contradicted these representations.

210. Defendant's actions, representations, and misrepresentations demonstrate callous disregard for not only the rule of law but also public health. Indeed, as a direct result of Defendant's actions, patients who should never have been taking Subsys have been harmed or died as a result of their prescription for off-label use.

211. Defendant owed Plaintiff and the Class Members a duty to disclose, truthfully, all the facts concerning the Subsys prescriptions Defendant sought to have Plaintiff provide coverage for.

212. Plaintiff and the Class Members were not aware of the concealed and misrepresented material facts referenced above, and they would not have acted as they did, had they known the truth.

213. As a direct and proximate result of Defendant's fraudulent scheme, Plaintiff and the Class Members sustained damages when they paid for Subsys prescriptions which should not have been covered because they were for off-label uses.

214. Defendant is liable to Plaintiff for damages in an amount to be proven at trial. Moreover, because Defendant acted wantonly, maliciously, oppressively, recklessly, deliberately, and with intent to defraud Plaintiff and the Class Members for the purpose of enriching themselves at Plaintiff's detriment, Defendant's conduct warrants substantial punitive and exemplary damages in an amount to be determined at trial.

COUNT IV
UNJUST ENRICHMENT

215. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

216. Defendant has benefitted from improperly obtaining prior authorizations from Plaintiff and the Class Members and thereby obtaining coverage for Subsys prescriptions which should not have been covered by Plaintiff and the Class Members. Defendants defrauded Plaintiff and the Class Members into paying for Subsys prescriptions which were for off-label uses and contrary to the medication's FDA-approved indication.

217. Defendant has received and retained unjust benefits from Plaintiff and the Class members, in the form of costs paid, copayments, and coinsurance payments, and inequity has resulted. It is inequitable and unconscionable for Defendant to retain these benefits.

218. Because Defendant concealed its fraud and deception, Plaintiff and the Class Members were not aware of the true facts concerning the Subsys scheme described herein and did not benefit from Defendant's misconduct.

219. Defendant knowingly accepted the unjust benefits of its fraudulent conduct.

220. As a result of Defendant's misconduct, the amount of their unjust enrichment should be disgorged and returned to Plaintiff and the Class Members, in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully request the following relief:

a. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(b), b(2) and/or (b)(1), and direct that reasonable notice of this action, a s provided by Federal Rule of Civil Procedure 23(c)(2), be given to the Class and declare Plaintiff as the representatives of the respective Class they seek to represent, and appoint their attorneys as Class Counsel;

b. Enter judgments against Defendant and in favor of Plaintiff for violations of the federal and common laws and legal standards invoked in this Complaint;

c. Order Defendants to pay pre-judgment and post-judgment interest as provided for by law or allowed in equity;

d. Award Plaintiff (three times overcharges) the amount to be determined at trial;

e. Award Plaintiff the costs of suit, including reasonable attorneys' fees as provided by law, including under RICO, and the common fund doctrine;

f. Order that Defendant must notify each and every individual who paid for the off-label use of Subsys about the pendency of this action so that they may obtain relief from Defendant for their harm; and

g. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38, Plaintiff demands a trial by jury on all issues so triable.

RESPECTFULLY SUBMITTED on this the 22nd day of August, 2018.

Respectfully submitted,

/s/*Tracy L. Turner*
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CERTIFICATE OF SERVICE

I hereby certify that on August 22, 2018, a true and correct copy of the foregoing was electronically filed using the CM/ECF system, which will send notification of such filing to counsel for Defendants.

/s/ Tracy L. Turner
Tracy L. Turner